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July 8, 1999

Dockets Management Branch (HFA-305)
FOOD and DRUG ADMINISTRATION
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: ANPRM (Docket No. 98N-1170)

Dear Sir or Madam:

Thank you for the opportunity to participate in this important comment period. Universal Insurance Facilities, Ltd. is the program manager for AIG (the largest insurance company in the world). Universal Insurance is the premier insurance program for indoor tanning salons and experiences first hand any claims arising from incidents where clients claim they were damaged from tanning. You may be surprised at how low these incidents are and this information should be very beneficial to the review process.

We believe this low incident rate is due largely to the fact that the current FDA Guidelines that are in place are appropriate and prudent for all indoor tanners. Universal Insurance insures more than 2,000 salons nationwide. Out of these 2,000 salons, only 29 claims were filed in 1998. Out of those 29 claims, only 7 closed with payment. That is less than 1%! We have five years worth of data which supports this extremely low incident claim rate. There has never been a year when more than 29 claims were filed. To further illustrate this point, we experience a much higher claim count for property type claims which would include fire, wind, trip and fall, theft, etc. In fact, this ratio of claims is much higher at almost 7%, and most of these do close with a payment made to the claimant.

This data supports the theory that the current exposure schedules are within reasonable guidelines and should not be altered. Additionally, current labeling also should be adequate based on historic results. The current requirements as stated by the FDA in its 21 CFR Part 1040 - - Performance Standards for Light - Emitting Products includes warning statements relating to overexposure,

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ultraviolet radiation, the risks of skin injury and allergic reactions, premature aging of the skin and skin cancer. Obviously, these warnings are being read and noted by tanners based on the fact that the claims rate is almost non-existent in the indoor tanning industry. It can be concluded from this evidence that tanning salon operators are complying with the manufacturers recommended exposure schedules and educating their clients on responsible and gradual tanning.

In your ANPRM you reference "recent advances in photobiological research" as a reason to propose changes. As a leading insurer specifically for the indoor tanning industry we are not aware of any specific research that has been conducted that relates directly to indoor tanning and exposure schedules. The research that the FDA references relates to UV exposure and skin cancer, photoaging and photoimmunological effects. Again, to our knowledge, this research was not conducted as it relates specifically to indoor tanning.

We feel that our data provides a stronger argument for leaving the standards in place as they were amended in September 1986. The research referenced in the ANPRM does not even relate directly to UV exposure through indoor tanning.

Thank you for allowing these comments to be included in your review period. If the current guidelines suggested by the FDA were in need of change, this would be reflected strongly in a much higher number of insurance claims. It is obviously not. We ask you to consider this as you propose changes.

Sincerely,



Randy Tipton
Vice President

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